ORIGINAL

FILED
U.S. DISTRICT COURT
DISTRICT OF WYOMING

SEP - 7 2005 2:40 pm

Stephan Harris, Clerk
Casper

Kathleen B. Dixon, Esq.
Stefanie L. Boster, Esq.
MURANE & BOSTWICK, LLC
201 North Wolcott
Casper, Wyoming 82601
Telephone: (307) 234-9345
Facsimile: (307) 237-5110

Thomas N. Alfrey, Esq.
Robert J. Zavaglia, Jr., Esq.
TREECE, ALFREY, MUSAT & BOSWORTH, P.C.
999 18th Street, Suite 1600
Denver, Colorado 80208
Telephone: (303) 292-2700
Facsimile: (303) 295-0414

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF WYOMING

BRIAN M. RENOVITCH, Plaintiff, v. TETON COUNTY HOSPITAL DISTRICT, d/b/a ST. JOHN'S MEDICAL CENTER, a Wyoming corporation, and SYNTHES (USA), a Pennsylvania general partnership, Defendants.	)	Civil Action No. 04-CV-188-J

MOTION IN LIMINE RE: UTILIZATION OF TESTIMONY OF REINHOLD DAUSKARDT, PH.D.

Defendant Synthes (USA) ("Synthes"), by and through counsel, Murane & Bostwick, LLC, and Treece, Alfrey, Musat & Bosworth, P.C., hereby submits this Motion in *Limine* re:

Utilization of Testimony of Reinhold Dauskardt, Ph.D., and in so doing requests that this Court enter an Order as follows:

That Plaintiff, his attorneys, and any witnesses be instructed not to bring before the jury either directly or indirectly, any suggestion of evidence or argument regarding any testimony or opinions rendered by Plaintiff's designated expert witness Reinhold Dauskardt, Ph.D., involving medullary tubes for the purpose of inferring or establishing either knowledge or a duty on Synthes in any manner.

BACKGROUND

1. This action arises out of a surgical operation which took place on December 1, 2000. During this operation, a medullary tube was inserted into Plaintiff's leg as part of a procedure to repair Plaintiff's broken tibia. In the course of this procedure, a portion of the medullary tube fractured. Plaintiff's physician failed to notice that pieces of the tube remained inside Plaintiff's medullary canal at the conclusion of this surgery. That the tube even fractured remained undetected by Plaintiff's physician for two days. A follow-up surgery to remove the pieces of tube was performed on December 19, 2000.

2. It is uncontested that in January of 1993 or earlier, Synthes sold the medullary tube here at issue to St. John's Medical Center, and that this single tube was used by St. John's physicians in procedures similar to Plaintiff's for at least seven years. It is also uncontested that this tube at issue was manufactured in Switzerland by a company called Mathys sometime prior to its sale in January of 1993 out of a material known as Nylon-6/6.

3. Plaintiff now asserts claims against Defendant Synthes for loss of chance, strict product liability, and negligence. Sec. Am. Compl. ("Complaint") ¶¶ 41-55. Plaintiff also seeks punitive damages. *Id.* at ¶¶ 56-60. Plaintiff is anticipated to offer in his case-in-chief on those duty-based claims that Synthes had knowledge indicating the potential failure of Nylon-6/6 in this application (i.e., construction of the medullary tube), and therefore had a duty to warn prospective consumers of that potential failure.

4. On May 20, 2005, Plaintiff designated Reinhold H. Dauskardt, Ph.D., as an expert witness. Plaintiff's Designation of Expert Witnesses, May 20, 2005, all relevant portions attached hereto as **Exhibit A.** In his designation, Plaintiff states that Dr. Dauskardt will testify as to the following:

> . . . that statements and/or warnings given by Synthes are insufficient and inaccurate; further a medullary tube may only be safely used for up to twenty five (25) autoclave cycles and Synthes should so warn; further, the probability of nylon 6/6 to fail was known and Synthes' own testing recognized these physical properties of nylon 6/6; further, the check of elasticity proposed is scientifically inaccurate; further, Synthes' proposal to check the tube is unsafe and no protocol is provided, nor are there workable procedures/tests to check for 'elasticity' in the hospital setting, nor would this be a proper form of testing.

Ex. A at pp. 15-16. The bases for these opinions are derived from a single study which Dr. Dauskardt conducted entirely independent of and unrelated to Plaintiff's injury first published in the summer of 2004. *See id.* at Opinion of Reinhold Horst Dauskardt, Ph.D., pp. 5-7. Dr. Dauskardt's research upon which that article was based did not begin until

2003. *See* Deposition of Reinhold Dauskardt, Ph.D., at 10:22-13:15, all relevant portions attached hereto as **Exhibit B**.

5. Dr. Dauskardt attached an extensive list of publications and presentations to his resume in disclosure for this lawsuit. Only one, however, addresses the study of medullary tubes: a publication he co-authored titled *Failure of a Medullary Tube: A Materials Analysis* ("Article"). **Ex. A**. It is this solitary five (5) page publication--unrelated to Plaintiff's case--upon which Dr. Dauskardt bases his opinions surrounding the particular medullary tube at issue. *Id.* at Opinion of Reinhold Horst Dauskardt, Ph.D. pp. 5-7.

6. Dr. Dauskardt's study, upon which his opinions are based, solely considers the long-term effect of steam sterilization, commonly referred to as "autoclaving," on the medullary tube sold by Synthes. *Id.* at Art. *in toto*. Discovery in this matter is now closed, and it is uncontestable that Dr. Dauskardt's Article is the first and only published study on the effect of autoclaving on Synthes' medullary tube.

7. There is no dispute that over a decade passed between the actual manufacture and sale of the medullary tube used in Plaintiff's December 1, 2000, surgery and the date of publication (and, thus, public availability) of Dr. Dauskardt's Article.

ARGUMENT

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or

> education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

However, the "touchstone" of admissibility is helpfulness to the trier of fact. *Werth, v. Makita Electric Works, Ltd.*, 950 F.2d 643, 648 (10th Cir. 1991).

Rule 702 "imposes upon the trial judge an important 'gate-keeping' function with regard to the admissibility of expert opinions." *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969 (10th Cir. 2001), *citing Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). In order to determine whether an expert's opinion is admissible, a trial court must undergo a two-step analysis. First, the court must determine whether the expert is qualified by "knowledge, skill, experience, training or education." FED. R. EVID. 702; *see also Ralston, supra*. Second, if the expert is so qualified, the trial court must then determine whether the expert's opinions are "reliable" under the principles set forth in *Daubert*. *See Ralston, supra*.

In determining whether an expert is qualified to testify, the court must consider the expert's qualifications as to the particular issue for which the expert's testimony is being offered. *Kumho Tire Company, Ltd. v. Carmichael, supra*, 526 U.S. 137, 154, 119 S. Ct. 1167, 1177 (1999). It is for that issue that the witness must possess expert qualifications. *See Renaud v. Martin Marietta Corp.*, 972 F.2d 304, 308 (10th Cir. 1992).

The trial court has "wide latitude . . . in exercising its discretion to admit or exclude expert testimony." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 883 (10th Cir. 2005) (internal quotations omitted).

Dr. Dauskardt's 2003 study and 2004 Article are irrelevant to the claims at issue in this action, and no justifiable basis allows his opinions to be submitted to the jury as the basis for finding any duty on behalf of Synthes to Plaintiff.

Dr. Dauskardt's testimony is properly be excluded as it is irrelevant to the case at issue. Under FED. R. EVID. 401, only relevant evidence is admissible at trial. The Federal Rules define "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FED. R. EVID. 401. Even so, "relevant [] evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury[.]" FED. R. EVID. 403.

It is within the sound discretion of the trial court to determine whether certain evidence is relevant to the issue before the jury. *Greenberg v. Service Business Forms Industries, Inc.*, 882 F.2d 1538, 1543 (10th Cir. 1989).

To support Plaintiff's claims of strict products liability and negligence, Plaintiff alleges that "the medullary exchange tube, when used for its intended use, will undergo changes" making it dangerous, Compl. ¶ 27, and that, with such knowledge, Synthes "distributed the [tube] with inadequate instructions for use, [and] inadequate warning regarding the risks for breakage[,]" *id.* ¶ 29; *see also id.* ¶¶ 41-55.

Based on review of Plaintiff's Designation of Expert Testimony, Plaintiff intends to offer the testimony of Dr. Dauskardt with the hope that his single study will persuade the jury to find that Plaintiff's medullary tube was defective and that, based on those opinions, the jury will infer that Synthes knew of such defect and failed to provide proper warnings and/or instructions--

either when it sold the medullary tube to St. John's in January of 1993, or in the intervening time between that sale and Plaintiff's December 1, 2000, surgery. *See* **Ex. A**; Compl. *in toto*. Such presentation is impermissible under *Kumho Tire* as Dr. Dauskardt's expertise in materials science does not comport with that particular issue for the purpose it is being offered. *Kumho Tire Company, Ltd.*, 526 U.S. at 154; *Renaud*, 972 F.2d at 308.

Dr. Dauskardt's study was not, however, a foray into the failure of any particular tube such as the one at issue here, but instead was a generalized investigation of Synthes medullary tubes only. Indeed, the study upon which his Article was based, conducted in 2003, utilized "new" nylon 6/6 medullary tubes for testing, and is the *only* study submitted in discovery in this case by any person, party, non-party witness, or in any other method of discovery, which investigates the potential long-term effect of autoclaving "unused" medullary tubes produced circa 2003. **Ex. A**, Art. at 879, 882 n.1-3. Conversely, nothing in either the Article or Dr. Dauskardt's deposition speak to the issue of Synthes' knowledge during the only relevant time period to this action (1993-2000), nor could Dr. Dauskardt offer any such opinions at trial.

Because Dr. Dauskardt's 2003 study did not take into account the specific circumstances surrounding the fracturing of Plaintiff's medullary tube, Dr. Dauskardt's Article and opinions as set out in his expert designation and report cannot afford reliable conclusions which are applicable to the case at hand as to Synthes' knowledge and/or duties prior to the Article's publication in 2004. Utilization of these items for any such purpose has no base in relevancy as Dr. Dauskardt is not a fact witness to these proceedings, has no knowledge and cannot testify on behalf of Synthes as to *its* knowledge, the subject and discussions of his research on medullary

tubes post-dates the relevant inferential period necessary to support Plaintiff's duty claims by a decade, and Dr. Dauskardt is admittedly not a standard of care expert in medical device manufacture and sale--either now or as of the date when the actual tube here at issue was purchased by St. John's. *See* **Ex. A** *in toto*. Dr. Dauskardt, a materials scientist who in layman's terms researches why things break, is neither qualified nor experienced to offer testimony inferring a duty on Synthes. As such, his opinions cannot be used to support such an inference. *Kumho Tire Company, Ltd.*, *supra*; *Renaud*, *supra*.

Even if Dr. Dauskardt's study, Article, and opinions as designated were relevant to the time period and issues which would speak to any of Plaintiff's duty claims, for the very same reasons described above these items are so substantially outweighed by the unfair prejudice of implication as to be prohibited from evidence under FED. R. EVID. 403.

In sum, any testimony presented by Dr. Dauskardt for the purpose of inferring or establishing a duty on Synthes would be unhelpful to any finder of fact, unfairly prejudicial to Synthes, and is properly barred from these proceedings.

CONCLUSION

FOR THE FOREGOING REASONS, Defendant Synthes requests that this Court enter an Order barring expert witness Reinhold Dauskardt, Ph.D.'s opinions in these proceedings in any manner inferring a duty of any sort on Synthes, and grant Synthes any other such relief as this Court deems just and proper.

Respectfully submitted this ~~6~~ 7 day of September, 2005.

Kathleen B. Dixon

Kathleen B. Dixon
Stefanie L. Boster
MURANE & BOSTWICK, LLC
201 North Wolcott
Casper, Wyoming 82601-1930
(307) 234-9345

and

Thomas N. Alfrey
Robert J. Zavaglia, Jr.
TREECE, ALFREY, MUSAT & BOSWORTH, P.C.
999 Eighteenth Street, Suite 1600
Denver, Colorado 80202
(303) 292-2700
Attorneys for Defendant Synthes (USA)

CERTIFICATE OF SERVICE

I hereby certify that on this 7 day of September, 2005, I served a true and correct copy of the foregoing **MOTION IN LIMINE RE: UTILIZATION OF TESTIMONY OF REINHOLD DAUSKARDT, PH.D.** upon all counsel of record in this action, by depositing the same with the United States Postal Service, first class postage pre-paid, as follows:

R. Michael Shickich, Esq.
111 West Second Street, Suite 500
Casper, Wyoming 82601

Frederick J. Harrison, Esq.
Post Office Box 1066
Rawlins, Wyoming 82301-1066

Frank D. Neville, Esq.
Nicol M. Thompson, Esq.
WILLIAMS, PORTER, DAY & NEVILLE, P.C.
Post Office Box 10700
Casper, Wyoming 82602-0700

Kathleen B. Dixon

Kathleen B. Dixon

EXHIBIT A

Motion *in Limine* Re: Utilization of Testimony of Reinhold Dauskardt, Ph.D.

Brian M. Renovitch v. Teton County Hospital District et al.
U.S.D.C., District of Wyoming
Docket No. 04-CV-188-J

5/20/05

RECEIVED
MAY 2 3 2005

R. Michael Shickich
Law Offices of R. Michael Shickich, L.L.C.
111 West 2nd Street, Suite 500
Casper, WY 82601
(307) 266-5297
(307) 266-1261 fax

Frederick J. Harrison
Frederick J. Harrison, P.C.
P.O. Box 1066
Rawlins, WY 82301-1066
(307) 324-6639
(307) 324-4444 fax

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

BRIAN M. RENOVITCH Plaintiff, v. TETON COUNTY HOSPITAL DISTRICT d/b/a ST. JOHN'S MEDICAL CENTER a Wyoming Corporation and SYNTHES (USA), a Pennsylvania General Partnership, Defendants.	Civil Action No. 04-CV-188 J

PLAINTIFF'S DESIGNATION OF EXPERT WITNESSES

Pursuant to this Court's order on initial pretrial conference and U.S.D.C.L.R. 26.1(f), the Plaintiff hereby designates his experts as follows:

EXHIBIT
A

Renovitch has received, as well as the medications which he was prescribed for depression/anxiety. Further, Dr. Kahn will testify as to the effects Mr. Renovitch's injuries have had upon his professional and personal life. Also, Dr. Kahn will testify as to Mr. Renovitch's future prognosis and diagnosis. Dr. Kahn's opinions are set forth more fully in his report attached hereto. Dr. Kahn's opinions are based on discovery which has occurred and/or has been previously provided between the parties and various interviews he conducted. It is expected Dr. Kahn will be deposed during which his opinion may be more fully explored, and Plaintiff reserves the right to utilize any opinion provided in the course of such discovery. Dr. Kahn's report, Curriculum Vitae, prior testimony, and fee schedule are attached hereto as Exhibit 6.

7. **Reinhold H. Dauskardt, Ph.D.**
Professor and Associate Chair; Department of Materials Science and Engineering
Stanford University
416 Escondido Mall, Bldg. 550, Rm. 550G
Stanford, CA 94305-2205
(650) 725-0679

Dr. Dauskardt will testify as to his knowledge, skill, experience, training, testing, and/or education regarding materials and engineering. It is expected Dr. Dauskardt will opine that statements and/or warnings given by Synthes are insufficient and inaccurate; further, a medullary tube may only be safely used for up to twenty five (25) autoclave cycles and Synthes should so warn; further, the probability of nylon 6/6 to fail was well known and Synthes' own testing

recognized these physical properties of nylon 6/6; further, the check of elasticity proposed is scientifically inaccurate; further, Synthes' proposal to flex the tube is unsafe and no protocol is provided, nor are there workable procedures/tests to check for "elasticity" in the hospital setting, nor would this be a proper form of testing. Dr. Dauskardt's opinions are more fully set forth in his expert report attached hereto. Dr. Dauskardt was the lead scientist and author of *Failure of a Medullary Tube: A Materials Analysis*, published July 16, 2003. Dr. Dauskardt will set forth opinions which derive out of and/or are consistent with that study. Dr. Dauskardt's opinions are based on those records and discovery which has occurred and/or has been previously provided between the parties, the studies he has performed and/or referenced, acceptable literature, and independent testing which he has conducted. It is expected Dr. Dauskardt will be deposed during which his opinion may be more fully explored, and Plaintiff reserves the right to utilize any opinion provided in the course of such discovery. Dr. Dauskardt's report, referenced article, Curriculum Vitae, and fee schedule are attached hereto as Exhibit 7.

8. **Suzanne Parisian, M.D.**
Medical Device Assistance, Inc.
7117 N. 3rd Street
Phoenix, AZ 85020
(602) 354-8491

Dr. Parisian will testify as to her knowledge, skill, experience, training, and/or education regarding FDA and medical standards. She is expected to set forth opinions consistent with

Opinion of

REINHOLD HORST DAUSKARDT, Ph.D.

Professor of Materials Science and Engineering, and

Associate Chair of the Department

Department of Materials Science and Engineering

416 Escondido Mall, Bldg. 550, Rm. 550G

Stanford University

Stanford, CA 94305 - 2205

On

Fracture of a Synthes medullary exchange tube used in the 12/01/2000 surgery

of Mr. Brian Renovitch

May 17, 2005

Based on my review of relevant material concerning the fracture of a Synthes medullary exchange tube (herein after referred to as tube) used in the 12/01/2000 surgery of Mr. Brian Renovitch, together with my own published study of the effects of repeated autoclaving on the mechanical behavior of such medullary exchange tubes that would affect their propensity to fracture, I have been able to form opinions of various factors concerning this incident. All opinions set forth are within a reasonable degree of materials science and engineering probability.

To date, the material that I have analyzed includes several depositions of persons with knowledge of the incident or the Synthes product, deposition exhibits and discovery produced by defendants that include but are not limited to:

PLAINTIFF'S EXHIBIT 7

photographs of the fractured medullary exchange tube,

medical records from St. John's Medical Center,

Western Wyoming Pathology Report, December 21, 2000,

Synthes documents of selected dates from 1975 to 2004 including Manual/Catalog, AO/ASIF Universal Nail Product Profile, The Universal Nailing System Technique Guide, The Titanium Tibial Nail System Solid and Cannulated Nails,

Synthes – Checklist a guide to care and maintenance of the AO/ASIF Instrumentation, Synthes AG, 1986,

Synthes - Table of Medullary Tube Complaints - Rebecca Black SYN0607 – 0610,

Synthes - For Personal Attention of the Operating Surgeon SYN0525 – 0534,

Synthes - Mechanical Testing Laboratory results SYN0583 – 0605,

Mechanical Testing Laboratory results SYN0539 – 0581.

The comments in this document also include opinions that derive from my paper entitled "Failure of Medullary Tubes: A Materials Analysis," by M. B. Taub, G. Wera, R. H. Dauskardt and D. G. Mohler, and published in Injury, International Journal of the Care of the Injured, 35, 878 – 882, 2004,

and from other published papers including:

"Rare Complication of Segmental Breakage of Plastic Medullary Tube in Closed Intramedullary Nailing," authored by D. Ip, W.C. Wu, and S.H. Wong, Injury, Int. J. Care Injured, 32, 730 – 731, 2001,

"Closed intramedullary nailing complicated by breakage of plastic medullary tube," authored by S. P. Godsiff and M. B. Heywood-Waddington, Injury, British J. Acc. Surgery 24 [2] 136 – 137, 1993,

"Multiple Fracture of Medullary Tube During Intramedullary nailing of Long Bone fractures," by M.R. Vakharia, S. A. Lehto, D. G. Mohler, J. Ortho. Trauma, 14 [7] 514 – 517, 2000.

I have also consulted various published references on the structure, composition and properties of polymer materials including:

"The Physical Properties of Polymers Handbook," edited by James E. Mark, American Institute of Physics Press, Woodbury, New York, 1996.

Finally, I had the opportunity to examine personally the fractured medullary tube.

The incident in question involved the fracture of a Synthes nylon medullary tube during internal fixation of the fractured tibia of Mr. Brian Renovitch. The tube was used during the process of reaming out the medullary canal before final placement of an intramedullary nail. The medullary canal of the tibia was reamed with a bent tipped reaming rod that was exchanged for a straight wire once the canal was sufficiently reamed. The medullary tube maintains fracture reduction as the guidewires are exchanged within the medullary tube. During the surgical procedure, the medullary tube fractured and went unnoticed in the medullary canal resulting in the inability to insert the medullary nail. Attempts were made by the surgeon to remove the blockage, which at the time of the surgery appeared only as an unknown obstruction in the medullary canal.

Three segments of the fractured medullary tube were supplied to me for examination. The pieces appeared identical to those shown in the photographs of the fractured medullary exchange tube noted above, and described in the Western Wyoming Pathology Report.

One piece of the tube had the identification number 355.01 printed on one end. The tube was approximately 8 mm in diameter with a wall thickness of approximately 1.8 mm. The longest segment was approximately 215 mm in length, the next segment was approximately 150 mm in length, and the shortest segment was approximately 60 mm in length. The length of the three segments placed end-to-end therefore equaled approximately 425 mm. The second longest segment had white gauze wrapped around the tube towards one end. The tube appeared medium brown in color.

The ends of the tube segments exhibited brittle fracture surfaces, indicating that the tube had fractured into the segments described. Visible examination of the fracture surfaces with the unaided eye indicated brittle cleavage-like fracture surfaces with no evidence of ductility. The flared end of the medullary tube had also fractured in a brittle fashion, again with no apparent evidence of ductility or plastic deformation. In addition to the gross fracture surfaces noted above, there was also visible evidence of secondary cracking of the tube walls. For example, on the longest section of the tube, multiple cracks were apparent in the tube wall, occurring principally in the circumferential and longitudinal directions although other orientations were also noted. The cracks had arrested prior to causing catastrophic fracture of the tube. Slight circumferential ridges were noted on the tube surface with the unaided eye. The ridges did not extend completely around the tube diameter and were separated by approximately 1 mm.

There were also extensive scratches, marks and damage present on the shorter segments of the tube. The marks and damage observed are consistent with the surgeries performed.

All of the fracture surfaces and secondary cracks observed suggested that the plastic medullary tube had become severely embrittled and prone to brittle fracture. No evidence of local plasticity or ductility was noted that is typically associated with the ductility and fracture resistance of the nylon polymer from which the tube was constructed. The brittle fracture surfaces, secondary cracking and a lack of ductility together with the discoloration of the tube are, however, consistent with the severe embrittlement caused by the effects of repeated exposures of the tube to steam sterilization cycles that have been reported in several studies noted above.

Based on the information available to me and the fractured segments of the tube, it is not possible to determine exactly the applied loads that caused the tube to fracture. The fracture clearly occurred when the tube was in the intramedullary canal because that is where the fractured segments were subsequently found. The tube may have failed during insertion of the tube, during withdrawal of the reaming rod, or during subsequent operations that involved removal of the medullary tube. Given the extremely brittle nature of the nylon tube at the time of the surgery, the applied loads associated with routine surgical handling have been reported to cause fracture of medullary tubes in the published literature that are referenced above. The loading may have been associated with bending of the tube as it was inserted into the medullary canal. Bending of the tube may also have resulted during removal of the reaming rod with the bent tip from the tube. Tension or torsional loading of the tube may have occurred during removal of the tube. The main point being that both during insertion and removal, the applied loads employed would be sufficient to cause fracture of the embrittled tube. In my opinion, this happened in the present instance. On the other hand, a tube that was not embrittled would be able to sustain extremely large applied loads and deformations and it would be extremely difficult to fracture. In our own published study, we could not fracture unembrittled Synthes nylon 6/6 tubes in our mechanical test system even after imposing strains of 0.4 (40% elongation of the tube).

Based on published studies, FDA-MedWatch reports and Synthes Product Complaint Reports, there have been many reports of fracture of Synthes medullary tubes during routing use that have been related to embrittlement of the tube by repeated exposures to steam sterilization cycles. After such exposures, tubes have been noted to be severely discolored brown instead of the original creamy white color of the unembrittled material. The discoloration is also accompanied by the material becoming brittle and prone to fracture. Synthes evaluations of such product complaints together with their Product Manuals note the propensity of the nylon material to

become brittle and prone to fracture after repeated steam sterilization cycles. They advise users that the tube is autoclavable but should be checked for elasticity to ensure that the material has not become brittle. As I discuss below, however, the elasticity of the nylon material is relatively unaffected by the autoclave cycles. The material may discolor and become brittle, but the elastic properties remain largely unchanged. Measuring the elastic properties of the material, if this could be accomplished by hand in a hospital without mechanical test equipment, would therefore be a very insensitive measure of the brittle nature of the material.

The nylon 6/6 polymer from which the tubes are manufactured is a mechanically strong and tough polyamide compared to other polymer materials. Nylon 6/6 is the most common form of nylon resulting from the polycondensation product of hexamethylenediamine $H_2N - (CH_2)_6 - NH_2$ and adipic acid $HOOC - (CH_2)_4 - COOH$. The "6/6" designation refers to the number of carbon atoms in the diamine and the number of carbon atoms in the dibasic acid, respectively. Nylon 6/6 tends to crystallize more than some other forms of nylons. Nylon 6/6 is generally also more stiff compared to other nylon formulations. Nylons tend to crystallize as a result of hydrogen bonding between the carbonamid groups (- CO – NH -) that occupy regular sites along the polymer chain. The tendency to crystallize and be stiffer is related the higher CH_2/CONH- ratio of nylon 6/6 which also makes this nylon more prone to water absorption. Moisture is well known to effect the mechanical properties of nylon and the tensile strength at yield of nylon 6/6 decreases from ~ 80 MPa when tested dry (< 5% relative humidity), to values of ~ 30 MPa when the material is tested in water. Increased crystallization leads to a significant embrittlement making the material prone to brittle fracture.

The effects of repeated exposures of Synthes nylon 6/6 medullary tubes to steam autoclaving cycles was examined in a study conducted by myself and colleagues at Stanford University and described in the paper entitled "Failure of Medullary Tubes: A Materials Analysis," by M. B. Taub, G. Wera, R. H. Dauskardt and D. G. Mohler, and published in Injury, International Journal of the Care of the Injured, 2004. Salient details of the study are summarized below. The purpose of the study was to directly quantify the effects of repeated autoclaving cycles on the mechanical properties and failure characteristics of Synthes nylon 6/6 medullary tubes. New nylon 6/6 medullary tubes were exposed to autoclave cycles of 0, 5, 10, 25, 100, 200, and 400 exposures in a steam sterilizer. Following the steam sterilizer manufacturer recommendation, a 12-minute cycle involving a peak temperature of 408 K and a peak pressure of 250 mm Hg was used. Tensile test specimens were machined from the autoclaved medullary tubes for mechanical testing.

Tensile testing of the new and exposed tubes revealed a significant change in their mechanical properties as determined from the measured stress strain curve and the resulting failure behavior. Tubes exposed to 25 or fewer cycles of autoclaving did not fail catastrophically during testing. Engineering strains of 0.40 were achieved in these specimens without failure and the ultimate tensile strength was approximately 60 MPa, consistent with strength values commonly reported for nylon 6/6. This means that even after straining the tensile specimens by 40%, the material did not break. However, with increasing autoclave cycles, the material was observed to fail at engineering strains significantly less than 0.4. Both the yield stress and the ultimate tensile strength decreased markedly after 100 autoclave cycles. A marked change in color was observed when comparing the unexposed tube to autoclaved tubes. The unexposed tube was white, other tubes progress from yellow to brown as exposures increased.

A trend of increasingly brittle failure with increasing autoclave cycles was evident in all specimens subjected to greater than 25 cycles. While those tubes exposed to 25 or fewer cycles of autoclaving were able to undergo significant ductile plastic deformation, allowing for engineering strains of 0.40 without failing catastrophically during testing, those tubes exposed to a greater number of cycles fractured during the course of their loading. Tubes exposed to 200 or more autoclave cycles failed at very low strains, below 0.015, in a brittle manner with virtually no detectable plastic deformation.

An interesting observation of the study that is particularly pertinent to the product warnings noted in the Synthes product manual was revealed by analysis of the elastic response of the tubes after autoclave cycles. The elastic properties of the tube are characterized using the so-called Young's Modulus, which is the slope of the stress strain curve before the onset of yielding and plastic deformation. The Young's Modulus is therefore a measure of the stiffness of the material. In our study, we found that the elastic behavior of the material as characterized by the Young's Modulus was almost independent of the number of autoclave cycles. The tubes had an average Young's Modulus of 1500 MPa with a standard deviation of 10%. Therefore, while the nylon material became very brittle with increasing autoclave cycles, with significantly degraded yield strength, ultimate tensile strength, and fracture strain following yielding, the elastic behavior of the material was essentially unchanged.

It is important to note that the ductility and fracture resistance of materials is significantly dependent on their ability to undergo plastic rather than elastic deformation. This is clear in the present study where the nylon material became brittle with increasing autoclave cycles. However, the elastic behavior of the material was not significantly effected. Therefore, checking the material

for elasticity as noted in the Synthes Product Manual can not reveal if the material has become brittle. The brittleness of the material could only be determined by plastically deforming the material, a test which in my opinion is not only technically very difficult to achieve without the aid of a sophisticated mechanical testing machine, but is essentially a destructive test after which the tube could not be used. In addition, a potentially more insidious result of the check for brittleness suggested by Synthes is that it may actually introduce damage into the tube which could then cause fracture on subsequent use. My visual examination of the Renovitch tube clearly revealed secondary cracking of the tube. Cracks such as these may have formed during routine use of the tube but could also have resulted from flexing of the tube to determine if it had become brittle. So the unintended consequence of flexing the tube to determine if it has become brittle may well cause damage leading to premature fracture during routine use following such testing. In fact, this possibility for damage creation during flexing of the tube was admitted in the deposition of John Disegi, Group Manager in Product Development of Materials and Specifications, Synthes Corporation.

In my opinion, based on the materials I have examined, Synthes was well aware of the problem of the nylon 6/6 tube becoming discolored and significantly brittle with increasing autoclave cycles based on numerous product complaints, their own mechanical property study showing decreased ductility with increased autoclave cycles, and warnings in their product literature. However, Synthes provides no protocol for checking for the brittleness of tubes. Checking for elasticity as a measure of embrittlement frequently mentioned in their literature is scientifically inaccurate, vague in its description (in their depositions, John Disegi, George Mikhail and Frank Wilson could not even specify how much a tube should be flexed during testing for elasticity), difficult to perform accurately by hand, and could potentially introduce damage into the material that would subsequently lead to fracture. It is scientifically inaccurate because elasticity is not necessarily related to brittleness and fracture resistance, vague because it does not indicate exactly how or by how much the tube should be flexed to determine brittleness, difficult to perform accurately by hand, and ultimately could compromise the reliability of the tube by introducing damage in the tube that may lead to premature fracture on subsequent use.

There are many applications of materials such as components for aircraft and biomedical devices where safety is important and where complex degradation processes lead to the progressive deterioration of materials. These may result, for example, from the exposure of materials to corrosive or chemically hostile environments, from complex loading, and from temperature cycles. Although the detailed degradation processes are not always fully understood, safety criteria can be

specified based on a worst case analysis to ensure that catastrophic failure does not occur. Such an analysis may be based on empirical or phenomenological models developed from accelerated testing data. The results may involve specifications for the maximum loads or number of temperature excursions that the material may safely be exposed under specified conditions.

In all of the Synthes materials which I have examined, I have seen no such analysis or specific warnings on the number of autoclave cycles that the nylon 6/6 tube could be exposed without significantly compromising its reliability. At the very least, I would have expected a warning or recommendation not to use the tubes after a limited number of exposures to autoclave cycles. One of the recommendations that resulted from our study was that if medullary tubes are re-used, they must be replaced before 100 exposures to autoclave sterilization. Moreover, whenever the tubes are discolored or show obvious defects, they must be replaced immediately. Based on the increased number of medullary tube failures that I have now become aware of, I would actually propose an even more conservative maximum number of 25 autoclave exposures. This is where we first noted a degradation in mechanical properties in our published study.

I am aware of the Synthes position expressed by Scott Eden, Compliance Group Manager, that if the cause of a product complaint was considered by Synthes to be indeterminate or invalid, they would only look for a trend in such cases if there was more than five complaints filed in a quarter. I do not believe that there is any scientific basis for such a position. As complaints of tubes fracturing were being reported to Synthes, there should have been an immediate investigation as to the cause of the unexpected failures.

The Synthes Product Manuals note the danger of the tubes becoming brittle, but other than a vague and scientifically inaccurate check for brittleness, provide no recommendation on the maximum number of autoclave sterilization cycles that the tube can safely be exposed. As noted above, even if a degradation process is not fully understood, a conservative analysis and recommendation can be constructed. I noted in the deposition of John Disegi that attempting to specify a maximum number of autoclave sterilization cycles is not possible and would lead to "misinformation going to the customer." The reason cited was that the conditions of the autoclave cycles used in different hospitals may be different. This presumably means the sterilization temperature, pressure, time and chemical additives. I disagree with this assessment. A study such as the one reported by myself and colleagues at Stanford could have been easily used to specify a maximum number of autoclave cycles under defined autoclave conditions. Users could have been advised to use the same autoclave conditions. Additional warnings could have been given indicating that if the autoclave conditions were different, or other chemical additives were

present, the maximum number of cycles should be reduced. More detailed studies could have been undertaken to determine the maximum number of allowable cycles under a wider range of conditions. None of these precautionary notifications was provided to customers even as increased reports of medullary tube failures resulting from embrittlement during autoclaving cycles were being reported in the literature and directly to Synthes.

Reinhold H. Dauskardt
Professor and Associate Chair
Department of Materials Science and Engineering
Stanford University

Date: 5/20/05

Injury, Int. J. Care Injured (2004) 35, 878—882

ELSEVIER

INJURY
INTERNATIONAL JOURNAL OF THE CARE OF THE INJURED

www.elsevier.com/locate/injury

Failure of medullary tubes
A materials analysis

Marc Taub[a], Glenn Wera[b], Reinhold H. Dauskardt[a], David G. Mohler[c,*]

[a]*Department of Materials Science and Engineering, Stanford University, 416 Escondido Mall, Building 550, Stanford, CA 94305-2205, USA*
[b]*Department of Orthopaedics, Case Western Reserve University, University Hospitals of Cleveland, 11100 Euclid Avenue Cleveland, OH 44106, USA*
[c]*Department of Orthopaedic Surgery and Sports Medicine, Stanford University Medical Center, 454 Forest Ave, Palo Alto, CA 94301, USA*

Accepted 16 July 2003

KEYWORDS
Medullary tubes; Nylon;
Hardware failure;
Biomechanics;
Material science;
Orthopaedic; Trauma

Summary The objective of this study is to determine the effects of autoclaving on the stress, strain, ultimate tensile strength (UTS), fracture strain, modulus, and yield stress of nylon medullary tubes. There are three reports describing nylon medullary tube failure in the literature. All cases involved the use of nylon medullary tubes during open reduction internal fixation of fractured long bones. We demonstrated increased brittleness and decreased strength with increased exposure of medullary tubes to autoclaving, most dramatically after 100 autoclave cycles. Visual inspection of tubes is a clear indication of material degradation after repeated autoclaving. Furthermore, there is a significant difference in ultimate tensile strength ($P < 0.0001$) between tubes exposed to less than 100 sterilization cycles compared to tubes exposed to greater than 100 cycles. Likewise, there is a significant decrease in yield stress ($P < 0.0004$) between the same groups. We recommend disposal and replacement of nylon medullary tubes before they are exposed to 100 autoclaving cycles in order to avoid failure of the device.

Introduction

The purpose of this study is to quantify the brittleness and failure characteristics of nylon medullary tubes in orthopaedic surgery. There are only three reports describing four cases of nylon medullary tube failure in the literature.[1–3] All cases involved the use of nylon medullary tubes during open reduction internal fixation of fractured long bones. The device itself is used during the process of reaming out the medullary canal before final placement of an intramedullary nail. Intraoperatively, the medullary canal of a long bone is reamed out with a bent, olive-tipped guidewire that is exchanged for a straight wire once the canal is sufficiently reamed. The medullary tube maintains fracture reduction as the guidewires are exchanged within the medullary tube. Vakharia et al.[3] case report described the catastrophic failure of the tube as it shattered into multiple homogenous fragments that were difficult or impossible to recover from the medullary canal of long bones. As a follow-up to their discovery, we analyzed the medullary tubes for stress, strain, ultimate tensile strength (UTS), fracture strain, modulus, and yield stress after repeated exposures to steam sterilization cycles.

*Corresponding author. Tel.: +1-650-473-4580; fax: +1-650-363-1411.
E-mail address: docmohler@aol.com (D.G. Mohler).

0020-1383/$ — see front matter © 2003 Elsevier Ltd. All rights reserved.
doi:10.1016/S0020-1383(03)00307-3

Materials and methods

New nylon 6/6 medullary tubes (medullary tube, nylon 6/6; Synthes® Ltd., USA, Paoli, PA, USA) were exposed to autoclave cycles of 0, 5, 10, 25, 100, 200, 300 and 400 exposures in a Castle M/C3333 Steam Sterilizer (Castle, Division of the Sybron Corporation, Rochester, NY, USA). Following the manufacturer's suggestions, a 12 min cycle involving a peak temperature of 408 K and a peak pressure of 250 mmHg was used.

Tensile specimens were machined from the autoclaved medullary tubes for mechanical testing. The tubes were bisected along their lengths, leaving two equal segments with half-circular cross-sections. Individual specimens were then cut to 70 mm lengths. A necked region, with a width equal to 69% of the specimen cross-sectional width was machined into each sample to ensure that failure would initiate in the gauge length during mechanical testing.

Uniaxial tensile testing was performed using an MTS Bionix 200 mechanical test machine (MTS Systems Corp., Eden Prairie, MN, USA) and was conducted at a constant cross-head displacement rate of 0.5 mm/s. The extension at the specimen gauge length was obtained using an MTS extensometer with a 1 in. gauge length. The resultant force necessary to achieve these displacements was measured using a 1 kN load cell.

In order to determine the stress applied to the sample, the applied force was normalized over the cross-sectional area of the sample. Engineering stress (σ_E) was defined as the force applied to the specimen normalized over the original cross-sectional area of the specimen. Engineering strain was determined by normalizing the extension of gauge length over its original length. All tests were conducted until an engineering strain of 0.4 was achieved in gauge length or until the sample failed, whichever occurred first. Tubes that were exposed to less than 100 sterilizations were compared to those that had undergone greater than 100 exposures in ultimate tensile strength and yield stress. Statistical significance was determined by an unpaired, two-tailed, Student's *t*-test. A significance of $P < 0.05$ was considered significant.

Results

Visual inspection: A marked change in colour is evident in comparing the unexposed tube to autoclaved tubes. The unexposed tube is white, other tubes progress from yellow to brown as exposures increase (Fig. 1).

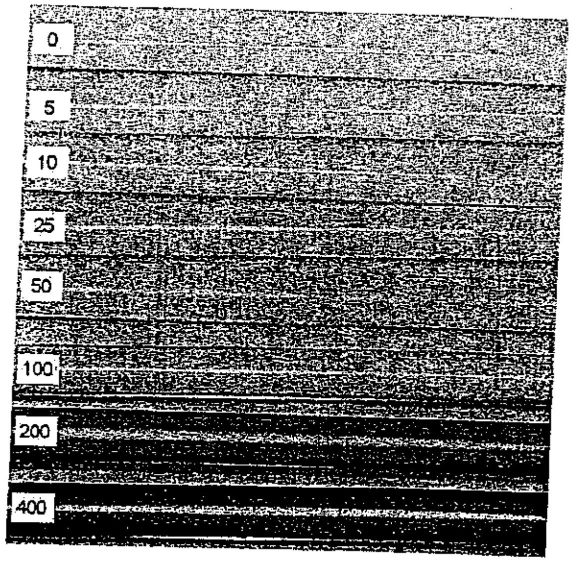

Figure 1 Autoclaved medullary tubes. The numbers on the left indicate the number of autoclave cycles performed on that specimen.

Tensile testing of these tubes reveals a change in failure behaviour with repeated autoclaving (Fig. 2). Tubes exposed to 25 or fewer cycles of autoclaving did not fail during testing. Engineering strains of 0.40 were achieved in these specimens without failure (Fig. 3). Tubes exposed to more than 25 cycles of autoclaving were observed to fail at engineering strains less than 0.4.

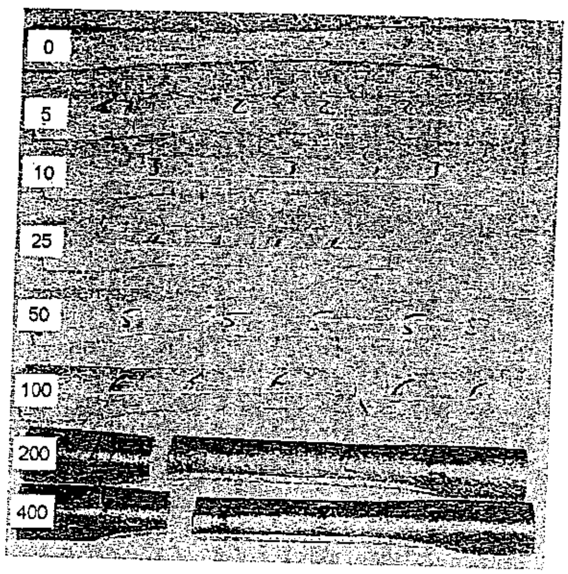

Figure 2 Autoclaved medullary tubes after tensile testing. The numbers on the left indicate the number of autoclave cycles performed on that specimen.

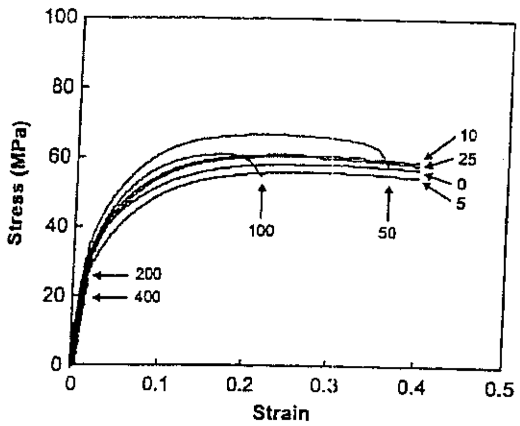

Figure 3 Plot of engineering stress vs. engineering strain for the autoclaved medullary tubes. There is a change from ductile to brittle failure with increasing number of autoclave cycles.

Engineering strains of 0.40 were achieved only in specimens that underwent 25 autoclave exposures or less. Greater than 25 autoclave exposures lead to catastrophic failure during testing at ε_E less than 0.40 (Fig. 3). A trend of ductile to brittle failure with increasing autoclave cycles is clear. Brittle failure is evident in all specimens subject to greater than 25 cycles.

Tubes exposed to 25 or fewer autoclave cycles were able to undergo ductile plastic deformation. Their integrity allowed for engineering strains of 0.40 without failing during testing. However, those tubes exposed to a greater number of cycles fractured during the course of their loading. In fact, those tubes exposed to 200 or more autoclave cycles failed at low strains, below 0.015, in a brittle manner, displaying almost no necking along the gauge length.

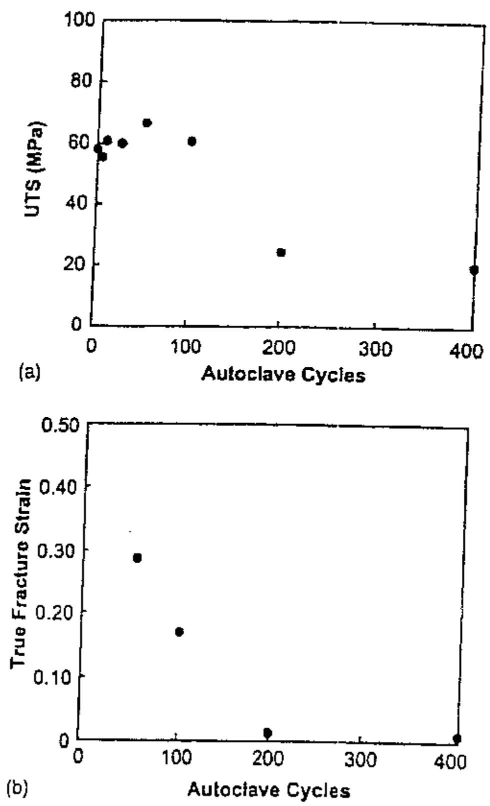

Figure 4 The ultimate tensile strength (UTS) is the maximum level of engineering stress achieved by the specimen during testing. At this stress level, localized failure of the specimen begins. Here we see that there is a dramatic decrease in UTS for those tubes exposed to greater than 100 autoclave cycles.

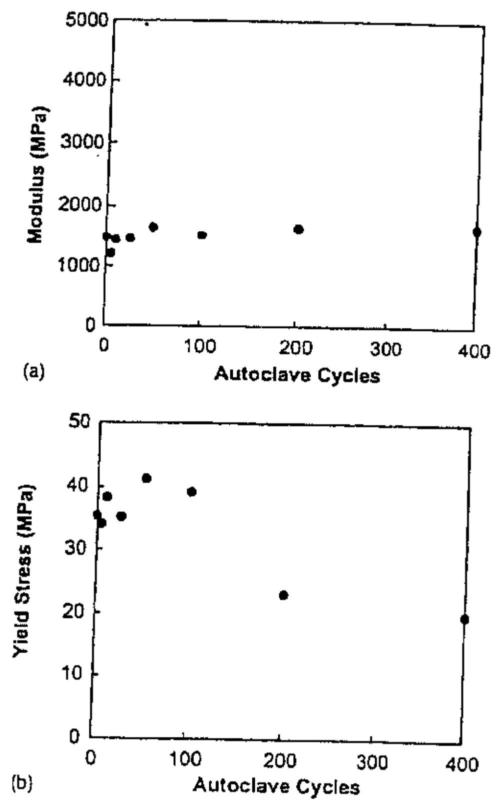

Figure 5 The modulus reflects the proportionality constant between stress and strain over the regime of elastic (recoverable) deformation. The modulus values are predominantly independent of autoclave cycling. The yield stress corresponds to the stress level at which the deformation regime transitions from elastic to plastic. These values were determined using a 0.002 offset strain. A dramatic decrease in yield stress is observed for those tubes exposed to greater than 100 autoclave cycles.

Tubes exposed to 25 or fewer autoclave cycles were able to undergo plastic deformation without catastrophic failure. Moreover, greater exposures lead to decreased plastic strain before failure. In fact, 200 or more exposures lead to failure at low strain in a brittle manner with virtually no plastic deformation.

An analysis of the elastic response of these tubes to an applied displacement reveals a near constant Young's modulus, independent of the number of autoclave cycles (Fig. 6). These tubes had an average Young's modulus of 1500 MPa with a standard deviation of 10%. The yield stress, the stress at which the elastic limit of the material has been reached and unrecoverable deformation commences, does however appear to be affected by the number of autoclave cycles. The yield stress displayed a bimodal distribution, with those tubes exposed to 100 or fewer cycles having a yield stress averaging 37 MPa with a standard deviation of 7.5%, and with those tubes exposed to 200 or more cycles having a much lower yield stress, averaging 22 MPa with a standard deviation of 9.9% (Fig. 6). The difference in yield stress among these two groups was significant ($P < 0.0004$).

It was also observed that the UTS for these tubes were also affected by the number of autoclave cycles they were exposed to. Those tubes exposed to 100 or fewer cycles had a UTS averaging 60 MPa with a standard deviation of 6.0%, while those tubes exposed to 200 or more cycles had a much lower yield stress, averaging 22 MPa with a standard deviation of 14.2% (Figs. 4 and 5). The difference between the two groups also demonstrated a significant weakness in UTS after 100 exposures ($P < 0.0001$).

Discussion

Typical stress—strain response from a polymer undergoing a tensile test includes an initial region of linear elastic response. The slope of a stress—strain curve within this region may be used to characterize this regime of recoverable elastic behaviour. The slope of this curve, which represents material stiffness, is known as the Young's or elastic modulus. The modulus is a property of the material that is independent of geometry. Rather, it is a product of intrinsic quality of the substance as well

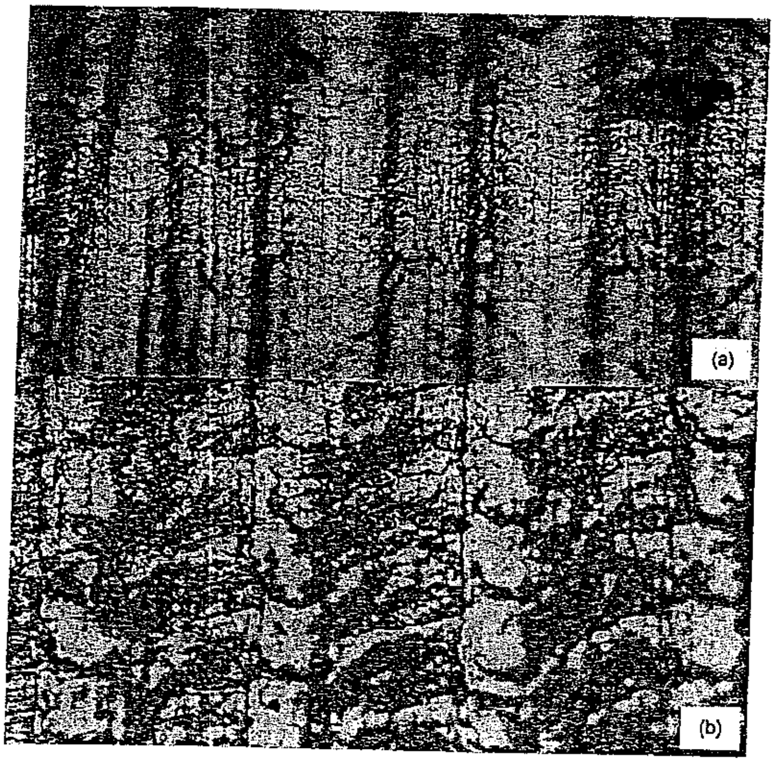

Figure 6 Micrographs of the exterior surfaces of: (a) a virgin tube and (b) a tube exposed to 400 autoclave cycles. The surfaces of both samples are marked by concentric rings that run along the length of the tubes. The ring-like surface flaws of are approximately 0.15 mm on center. Degradation of the surface finish of the tubes is also apparent with autoclave cycling.

as processing conditions such as autoclave exposures. Once the elastic limit of a material is reached, yielding occurs with plastic (unrecoverable) deformation. During the initial stages of plastic deformation, the cross-sectional area of the specimen decreases uniformly as the gauge length of the sample increases. However, after achieving UTS a neck forms at a particular point along the gauge length where cross-sectional area begins to decrease more rapidly. The UTS is the maximum point on the engineering stress (σ_E) engineering strain (ε_E) curve and represents the highest force necessary to deform the material.

Failure of nylon medullary tubes stems from a change in the mechanical behaviour of the tubes after repeated autoclave exposure. Moreover, a change in the mode of failure is engendered by autoclaving. After more than 100 autoclave cycles, the tubes fail in a brittle rather than plastic manner. Low levels of force lead to catastrophic failure and fragmentation of the tube because without plastic deformation, little or no energy dissipation is possible.

Interestingly, there is a continuous spiral which travels along the surface of the tubes. It appears to be a remnant of the machining process. The ring-like surface flaws of this spiral are about 0.15 mm on centre and their presence may concentrate stress and serve as nucleation points for small cracks which lead to failure as the curved, olive-tipped guidewire is exchanged during reaming of long bones (Fig. 6). Additionally, it is apparent from micrographs taken of the external surfaces of the tubes that there is a decrease in the quality of the surface finish with autoclave cycling that may serve to magnify the effects of any as-received surface flaws.

At centres such as ours where medullary tubes are re-used, they must be replaced before 100 exposures to autoclave sterilization. Since it may be difficult to track the number of uses per tube, we recommend inspecting the tubes prior to each use. Bending the tubes manually prior to use in surgery will likely break any defective tubes. Whenever the tubes are discoloured, stiff, or show obvious defects, they must be replaced immediately. It may be extremely difficult or impossible to retrieve nylon fragments of the tube in the event of catastrophic failure within the medullary canal of long bones. Furthermore, reduction and fixation of the fracture will be compromised by failure of the tube.[1–3]

References

1. Ip D, Wu WC, Wong SH. Rare complication of segmental breakage of plastic medullary tube in crossed intramedullary nailing. Injury 2001;32(9):730–1.
2. Godsiff SP, Heywood-Waddington MB. Closed intramedullary nailing complicated by breakage of plastic medullary tube. Injury 1993;24(2):136–7.
3. Vakharia MR, Lehto SA, Mohler DG. Multiple fracture of medullary tube during intramedullary nailing of long bone fractures. J Orthop Trauma 2000;14:514–7.

EXHIBIT B

Motion *in Limine* Re: Utilization of Testimony of Reinhold Dauskardt, Ph.D.

Brian M. Renovitch v. Teton County Hospital District et al.
U.S.D.C., District of Wyoming
Docket No. 04-CV-188-J

REINHOLD H. DAUSKARDT, Ph.D.,

called as a witness, after having been duly sworn by the Certified Shorthand Reporter to tell the truth, the whole truth, and nothing but the truth, testified as follows:

EXAMINATION

BY MR. ALFREY:

Q. Would you please state your name and your business address?

A. Reinhold Dauskardt. I work at the Stanford University Department of Material Science and Engineering.

Q. And for how long have you been employed there, sir?

EXHIBIT
B

A. Eleven years.

Q. Have you ever worked in the private sector?

A. I have not.

Q. Since you completed your formal education, you've always been involved in academia?

A. I was a staff scientist at the Lawrence Berkeley Laboratory. So that was not a complete academic position, but a purely research position.

Q. And your area of emphasis in your research is what, sir?

A. I study the mechanical behavior of materials,

A. It's merely reliability issues. How reliable will the device be? Will it survive in a physiological environment? Will it degrade as a function of time? This is exactly the area that I specialize in and have specialized in for nearly 20 years now.

So they would be interested in what are the underlying mechanisms that control the reliability of their device? How does -- how does this affect the longevity of the device? What is the probability the device might fail? What is the effect of environment? What is the effect of physiological loading or of other loading? What is the effect of handling the device? Anything that impacts the potential reliability of the device is something that we would be interested in.

Q. For your work in regard to this lawsuit, Doctor, did you have contact with anybody associated with Synthes?

A. No, I did not.

Q. And have you prior to this lawsuit evaluated any product made by Synthes?

A. Not to my knowledge, no.

Q. Before your work in -- before your work with Dr. Mohler back in 2003 in regard to medullary tubes, had you previously been involved with any study related to medullary tubes?

A. No, I had not.

Q. And how is it -- is 2003 the right time period?

A. I think that's about right, yes. I think that's about right.

Q. And how is it that you became involved in 2003?

A. Well, David Mohler arrived at my office one day and very persuasively argued that I should look at this particular medullary tube, which was failing. And first I wasn't interested because I wasn't sure that there was anything fundamental that would capture my basic scientific interest. But he was very persuasive, and, in fact, once he started to explain to me exactly what had happened in a number of procedures that he had undertaken, I became very intrigued.

This is something to me at the time that was absolutely shocking that a -- a simple tube like this made of a material that should never, ever fail was, in fact, failing in such a catastrophic fashion.

So clearly, the material had changed very substantially. It had become extremely unreliable. And I think the thing that really shocked me was just how traumatic it is if this simple little tube were to fail in the medullary canal, and how difficult it was.

He explained to me in great detail at the time how incredibly difficult it is to get out and how much

damage you do to the surrounding tissue.

So that actually got me very interested, and I then decided that I would, in fact, take on this project at the time with him, and I got a student involved, Mark Taub, who is the first author on the paper that we subsequently wrote, and we conducted the study.

Q. Did you know Dr. Mohler prior to that day he came into your office?

A. I did not. I believe he e-mailed me prior to arriving, but I did not know him, and that was the first time I met him.

Q. At any time in your relationship with Dr. Mohler did he present to you the tubes that had failed on two occasions that he was involved with?

A. He brought with him a medullary tube. But I don't believe he brought the tube that had failed.

Q. Was it your understanding the tube he brought to you was an unused tube?

A. I don't know that.

Q. All right, sir. Based on your examination of it and your subsequent work related to medullary tubes, do you now know whether it was a tube that had been used very infrequently, if at all?

A. Well, he -- when he first visited me, he brought a tube just to show me what it looked like. It

could have been anything. It could have been a bicycle tube at that point.

Subsequently, of course, we did work on Synthes tubes that were, according to my understanding, given to him by one of the Synthes reps. So that's what we actually conducted the study on.

However, initially when he came to visit me, he brought a tube, which I assume would have been a Synthes tube, just to show me what it looked like.

Q. Have you seen tubes manufactured by other companies than Synthes?

A. No, I have not.

Q. And I gather then you have not performed any type of study related to tubes made by others?

A. No, I have not.

Q. Okay, sir. You've brought with you today what we all understand to be the tube used in Mr. Renovitch's procedure of December 2000.

A. Mm-hm.

Q. Let me ask you, sir, I assume that what we're looking at today, this tube used in the December 2000 procedure on Mr. Renovitch, is in the same condition as when you received it?

A. Yes, absolutely.

Q. And this is in three different pieces?